

§ 864.9750

in subpart E of part 807 of this chapter subject to § 864.9.

[45 FR 60650, Sept. 12, 1980, as amended at 63 FR 59226, Nov. 3, 1998]

§ 864.9750 Heat-sealing device.

(a) *Identification.* A heat-sealing device is a device intended for medical purposes that uses heat to seal plastic bags containing blood or blood components.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 864.9.

[45 FR 60650, Sept. 12, 1980, as amended at 65 FR 2311, Jan. 14, 2000]

§ 864.9875 Transfer set.

(a) *Identification.* A transfer set is a device intended for medical purposes that consists of a piece of tubing with suitable adaptors used to transfer blood or plasma from one container to another.

(b) *Classification.* Class II (performance standards).

[45 FR 60651, Sept. 12, 1980]

PART 866—IMMUNOLOGY AND MICROBIOLOGY DEVICES

Subpart A—General Provisions

Sec.

866.1 Scope.

866.3 Effective dates of requirement for premarket approval.

866.9 Limitations of exemptions from section 510(k) of the Federal Food, Drug, and Cosmetic Act (the act).

Subpart B—Diagnostic Devices

866.1620 Antimicrobial susceptibility test disc.

866.1640 Antimicrobial susceptibility test powder.

866.1645 Fully automated short-term incubation cycle antimicrobial susceptibility system.

866.1700 Culture medium for antimicrobial susceptibility tests.

Subpart C—Microbiology Devices

866.2050 Staphylococcal typing bacteriophage.

866.2120 Anaerobic chamber.

866.2160 Coagulase plasma.

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866.2170 Automated colony counter.

866.2180 Manual colony counter.

866.2300 Multipurpose culture medium.

866.2320 Differential culture medium.

866.2330 Enriched culture medium.

866.2350 Microbiological assay culture medium.

866.2360 Selective culture medium.

866.2390 Transport culture medium.

866.2410 Culture medium for pathogenic *Neisseria* spp.

866.2420 Oxidase screening test for gonorrhea.

866.2440 Automated medium dispensing and stacking device.

866.2450 Supplement for culture media.

866.2480 Quality control kit for culture media.

866.2500 Microtiter diluting and dispensing device.

866.2540 Microbiological incubator.

866.2560 Microbial growth monitor.

866.2580 Gas-generating device.

866.2600 Wood's fluorescent lamp.

866.2660 Microorganism differentiation and identification device.

866.2850 Automated zone reader.

866.2900 Microbiological specimen collection and transport device.

Subpart D—Serological Reagents

866.3010 *Acinetobacter calcoaceticus* serological reagents.

866.3020 Adenovirus serological reagents.

866.3035 *Arizona* spp. serological reagents.

866.3040 *Aspergillus* spp. serological reagents.

866.3050 Beta-glucan serological assays.

866.3060 *Blastomyces dermatitidis* serological reagents.

866.3065 *Bordetella* spp. serological reagents.

866.3085 *Brucella* spp. serological reagents.

866.3110 *Campylobacter fetus* serological reagents.

866.3120 Chlamydia serological reagents.

866.3125 *Citrobacter* spp. serological reagents.

866.3135 *Coccidioides immitis* serological reagents.

866.3140 *Corynebacterium* spp. serological reagents.

866.3145 Coxsackievirus serological reagents.

866.3165 *Cryptococcus neoformans* serological reagents.

866.3175 Cytomegalovirus serological reagents.

866.3200 *Echinococcus* spp. serological reagents.

866.3205 Echovirus serological reagents.

866.3220 *Entamoeba histolytica* serological reagents.

866.3235 Epstein-Barr virus serological reagents.

866.3240 Equine encephalomyelitis virus serological reagents.

866.3250 *Erysipelothrix rhusiopathiae* serological reagents.